

AUG 20 2003

## 510(k) Summary

K031698

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**Submitter  
name, address,  
contact** Roche Diagnostics Corporation  
9115 Hague Road  
Indianapolis, IN 46250  
521 - 3723

Contact Person: Theresa M. Amrbose

Date Prepared: May 29, 2003

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**Device Name** Proprietary name: Elecsys® SHBG CalCheck

Common name: Calibration Verification Material

Classification name: Single (specified) analyte controls (assayed + unassayed)

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**Predicate  
device** The Elecsys® SHBG CalCheck is substantially equivalent to the currently marketed Elecsys® proBNP CalCheck (K020883).

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**Device  
Description** The Elecsys® SHBG CalCheck is a lyophilized product manufactured using SHBG in human serum/ horse serum matrix. The analyte is appropriately spiked into the CalCheck matrix to the correct concentration levels.

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## 510(k) Summary, Continued

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<b>Intended use</b>	The Elecsys® SHBG CalCheck is used in the verification of the calibration established by the Elecsys® SHBG reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.
<b>Comparison to predicate device</b>	The Elecsys® SHBG CalCheck is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Elecsys® proBNP CalCheck (K020883).
<b>Performance Characteristics</b>	The Elecsys® SHBG CalCheck was evaluated for value assignment and stability.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 20 2003

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Theresa M. Ambrose, Ph.D., FACB  
Regulatory Principal  
Centralized Diagnostics Regulatory Submissions  
Roche Diagnostics Corporation  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250

Re: k031698  
Trade/Device Name: Elecsys® SHBG CalCheck  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I  
Product Code: JJX  
Dated: August 5, 2003  
Received: August 6, 2003

Dear Dr. Ambrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

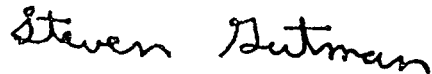
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): N/A K031698

Device Name: Elecsys® SHBG CalCheck

### Indications For Use:

Elecsys® SHBG CalCheck calibration verification solutions comprise three levels - low, mid, and high - each with a defined SHBG concentration. The low solution concentration is near the lower detection limit of the assay. The middle solution is in the middle or at a clinically critical point of the measuring range. The high solution is near the upper limit of the measuring range.

The Elecsys® SHBG CalCheck is intended for use in the verification of the calibration established by the Elecsys® SHBG reagent on Elecsys® 1010/2010/MODULAR ANALYTICS E170 immunoassay analyzers.

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Carol C. Benen for Jean Cooper, DVM  
Division Sign-Off

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

510(k) K 031698